IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362 Hon. David A. Faber
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665 Hon. David A. Faber

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE EXPERT TESTIMONY FROM DR. MICHAEL SIEGEL REGARDING PURPORTED OPIOID "OVERSUPPLY"

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INTRODUCTION[1]

Plaintiffs' expert Dr. Michael Siegel has invented a purported opioid "oversupply" analysis that has no grounding in real-world practice and that is unsupported by any reliable methodology. He should be excluded from testifying.

Dr. Siegel is an epidemiologist who has devoted his career to studying harm related to tobacco, alcohol, and firearms. He has never published on prescription opioids or devoted any meaningful professional attention to them. His most developed attempt at building expertise regarding these unique products is a failed attempt to publish a single paper on them that he abandoned after it was repeatedly rejected for publication. He has no expertise or qualifications that allow him to serve as an expert on the invented-for-litigation "oversupply" claim that has never been presented elsewhere.

Methodologically, Dr. Siegel's analysis is infected with unreliability at every step. He claims to calculate purported "oversupply" to five[2] individual pharmacies in Cabell County, but he does so by using unreliable national benchmarks and arbitrary population measurements for those five pharmacies. More broadly, his attempt to identify "oversupply" is wholly divorced from any real-world standards. Dr. Siegel's opinions are predicated on an alleged massive number of prescriptions that were not proper, but he has conceded that he could not tell whether individual prescriptions were legitimate or not. Finally, in attempting to blame Defendants for

[1] Dr. Siegel was not offered as an expert in Track 1, nor was there a *Daubert* motion that addressed a similar or identical issue to that raised herein.

[2] While Dr. Siegel purports to analyze distribution to eight pharmacies "in and around" Cabell County or in "nearby counties," *see* Siegel Report (Ex. A), at 35, 75, only five of these pharmacies are actually in Cabell County: Rite Aid #968 (*id.* at 64); Rite Aid #3311 (*id.* at 62); CVS 10566 (*id.* at 54); Fruth Pharmacy #5 (*id.* at 41, 53); and the Medicine Chest (*id.* at 42). The remaining pharmacies all fall outside of Cabell County—and in the case of the Westside

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this "oversupply," he invents a "public health responsibility" to prevent "oversupply" that consists of nothing more than impermissible legal opinion.

In sum, Dr. Siegel's opinions are built on a foundation that crumbles under even the slightest scrutiny. The assumptions that inform his "oversupply" computation in turn taint his opinion about "oversupply" itself, as well as Defendants' role in that purported "oversupply." All of his opinions should be excluded.

LEGAL AND FACTUAL BACKGROUND

A. Rule 702 Legal Standards

Courts have the responsibility to play a "gatekeeping role" with respect to experts. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595, 597 (1993). In performing this role, courts first must evaluate whether a witness is "qualified as an expert." Fed. R. Evid. 702. An expert must have "sufficient specialized knowledge to assist the [factfinder] in deciding the particular issues in the case." *Kumho Tire Co. v. Charmichael*, 526 U.S. 137, 156 (1999) (internal quotation marks omitted). To determine whether an expert has such specialized knowledge, courts look to "the proposed expert's full range of experience and training, not just his professional qualifications." *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012) (internal quotation marks omitted). Courts additionally must ensure "that an expert's testimony both rests on a *reliable* foundation and is *relevant* to the task at hand." *Daubert*, 509 U.S. at 597 (emphasis added).

"A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or

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Pharmacy in Oceana, it is a 2.5 hour drive from the County. *See* Siegel Dep. Tr. (Ex. B) at 350:4-351:3.

other valid methods." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (citing *Daubert*, 509 U.S. at 590, 592–93). Courts may consider several factors in assessing reliability, including: (1) whether the expert's theory or technique has been or can be tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and 5) whether the theory is generally accepted. *Daubert*, 509 U.S. at 593–94.

Relevant expert evidence is that which helps "the trier of fact to understand the evidence or to determine a fact in issue." *Id*. at 591 (internal quotation marks omitted). The proposed expert testimony must have "a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591. "The consideration has been aptly described … as one of 'fit.'" *Id.* at 591; *Garlinger v. Hardee's Food Sys., Inc.*, 16 F. App'x 232, 235 (4th Cir. 2001) ("The consideration of relevance requires the district court to determine whether the testimony 'fits' the instant case."). On the question of relevance or fit, courts recognize that an expert's "testimony must be sufficiently tied to the facts of the case that it will be of assistance to the factfinder in resolving a disputed fact." *Bourne v. E.I. Dupont de Nemours & Co., Inc.*, 189 F. Supp. 2d 482, 495 (S.D. W. Va. 2002) (citing *Kumho Tire*, 526 U.S. at 150). In other words, to "fit" the facts of the case, there "must be a valid … connection to the pertinent inquiry before testimony is admissible." *Id.* (internal quotation marks omitted).

In the bench trial context, where a judge rather than a jury sits as the factfinder, Rule 702 plays no less an important part in the consideration of expert testimony. *See UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres*, 949 F.3d 825, 832-33 (3d Cir. 2020) (recognizing that "Rule 702 applies whether the trier of fact is a judge or a jury," and noting that "the failure to

conduct any form of 'assessment' of an expert and the proposed testimony before admitting the testimony is an abuse of discretion"); *see also Kumho Tire*, 526 U.S. at 152, 158–59 (Scalia, J., concurring) (explaining that while district courts retain "latitude" to decide "how" to apply these requirements in a bench trial, that "is not discretion to abandon the gatekeeping function" or "perform the function inadequately. Rather, it is discretion to choose among *reasonable* means of excluding expertise[.]").

B. Factual Background

1. Dr. Siegel's Lack of Experience Regarding Prescription Opioids

Dr. Siegel is a physician and professor of public health in the Department of Community Health Sciences at the Boston University School of Public Health. Ex. A, at 4. He was, at one time, a practicing physician, but he has not been licensed to practice medicine since 1995, and has not treated a patient or prescribed an opioid since 1993. Ex. B, at 59:19-22; 62:1-12. Dr. Siegel is trained in epidemiology, but his public health experience has focused on tobacco use, alcohol, and firearms, Ex. A at 5; Ex. B at 62:13-18, which he admits are materially different products from prescription opioids. Ex. B at 86:11-20; 88:1-89:21. Indeed, Dr. Siegel's CV reflects that he has never published or presented on the topic of opioids or opioid supply, nor has he ever conducted an opioid "oversupply" analysis related to distributors before his participation in this case. Ex. A at Ex. B; Ex. B at 65:11-17, 66:10-68:1; 72:1-20. The closest he has come to publishing an article about opioids was a paper with a student that related to prescribing practices and overdoses, but despite submitting that paper to three different publications, it was never published, nor was it even sent out for peer review. Ex. B at 99:13-101:23.

2. Dr. Siegel's Expert Report And Methodology

Dr. Siegel offers two primary opinions. ***First***, he performs a calculation purportedly aimed at identifying an "oversupply" of prescription opioids into Cabell County and eight

specific pharmacies in and outside of the County. Ex. A at 32-38. Dr. Siegel established a nationwide "benchmark" using Census and ARCOS data to determine the average amounts of oxycodone and hydrocodone being distributed nationally in the United States. *Id.* at 34-35. Based on that data, he calculated the nationwide average distribution per adult at 0.15 dosage units per day, and per opioid-taking adult at 2.2 dosage units per day. *Id.* at 38. He then used that benchmark to evaluate the distribution of oxycodone and hydrocodone to the individual pharmacies by simply "dividing the number of dosage units supplied to the pharmacy per day by the adult population of the municipality in which that pharmacy is located." *Id.* at 34-35. Dr. Siegel calculated the percentage of adults using opioids per day to be 6.9%, based on a single study showing opioid use in the past 30 days. *Id.* at 35-36. The bulk of Dr. Siegel's report is then devoted to comparing the dosage units of oxycodone and hydrocodone distributed to the selected pharmacies and to Cabell County generally with the nationwide benchmarks in a purported "oversupply" analysis. *Id.* at 38-80.

Second, based on the results of his "benchmark" calculation and comparison, Dr. Siegel opines on what he calls a "public health responsibility" on the part of all "supply chain defendants" to prevent the "oversupply" of their products. Ex. A at 19-32. He lacks any foundation for this claimed "public health responsibility."

ARGUMENT

A. Dr. Siegel Is Not Qualified to Opine on Opioid "Oversupply" or on Distributor Obligations

As a threshold matter, Dr. Siegel lacks the most basic requirement to offer the opinions he seeks to give in this case. While Dr. Siegel may have experience in certain areas of public health, that experience does not qualify him to be an expert on the unique opinions on opioid "oversupply" and distributor obligations that he seeks to offer here.

In general terms, Dr. Siegel is a trained doctor who has not practiced medicine, been licensed to practice medicine, or prescribed a medication in nearly thirty years. Ex. B at 59:18-22. In fact, he has "never had . . . a regular [medical] practice," Ex. B at 62:5-6, and has never been board certified in any field. Ex. B at 61:13-16. Dr. Siegel is also an epidemiologist who focuses extensively on harms related to tobacco, alcohol, and firearms. His only foray into prescription opioid research is a single paper he wrote on prescription opioid prescribing rates and overdoses, which was rejected by three journals and was never peer-reviewed. Ex. B at 100:6-101:18. Dr. Siegel confirmed that he has never published or presented on prescription opioids. Ex. B at 66:10-68:1; 72:1-20.

Nothing in Dr. Siegel's background qualifies him to provide the novel opinions he seeks to provide here on alleged "oversupply" and distributor "public health responsibilities." He has never worked for the DEA, FDA, a pharmaceutical distributor, or a pharmacy. Ex. B at 62:21-63:9. He has never before analyzed alleged "oversupply" by distributors or at pharmacies.[3] Prior to this case, he had never held himself out to be an expert on the alleged "public health responsibilities" of distributors.[4] He has no relevant experience, and he draws on no existing body of science or literature addressing measures of opioid "oversupply" or distributor "public health responsibilities." Instead, he is manufacturing opinions in an area that neither he nor anyone else has addressed before. This fact alone calls into question the admissibility of his testimony. *See Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158 (4th Cir. 1998) (unpublished)

[3] Ex. B at 65:11-17 ("Q. Prior to this case, have you ever performed an analysis of alleged "oversupply" by distributors regarding prescription opioids? A. No. Q. Prior to this case, have you ever performed an analysis of alleged "oversupply" at pharmacies? A. No.").

[4] Ex. B at 78: 8-12 ("Q. . . .Have you ever held yourself out as an expert before this case on the public health duties of pharmaceutical companies and distributors? A. No.").

("Another significant fact weighing against admitting the testimony is where, as here, the expert developed his opinions expressly for the purposes of testifying.").

Plaintiffs appear to believe that Dr. Siegel's general public health qualifications and experience qualify him as an expert in "oversupply" and distributors' obligations.[5] That is not sufficient under *Daubert*. *See Lawrence v. Raymond Corp.*, No. 09 CV 1067, 2011 WL 348324, at *4 (N.D. Ohio Aug. 4, 2011) (citation omitted) ("[A] party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue."); *Kumho*, 526 U.S. at 156. Dr. Siegel's experience and training in public health does not provide him with specialized knowledge in "oversupply" or distributors' obligations. He therefore lacks qualifications to give the opinions he seeks to offer here, and his opinions must thus be excluded. *See In re: Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4072058, at *6 (N.D. Ohio Aug. 29, 2019) (excluding similar opioid expert whose "lack of relevant experience goes to the heart of his opinions and analysis, thereby, making them inadmissible").

B. Dr. Siegel's Methodology Is Unreliable

Dr. Siegel's "oversupply" opinions are based on two calculations that are infected with unreliability: (i) the assumed size of the population served by each pharmacy (based on the population of the town in which they are located); and (ii) the assumed percentage of opioid using adults nationwide. As discussed below, Dr. Siegelarrives at these facts based on multiple flawed assumptions that ultimately render them fundamentally unhelpful and inadmissible under Rule 702 and *Daubert*.

[5] Ex. B. at 97:14-22 ("Q. Do you consider yourself an expert on each of those topics - stair use in offices, soda company activities, breakfast cereal marketing, traffic fatalities, jello [sic] shots? . . . A. Yes, I think as a public

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Estimates about the population served. Dr. Siegel relies on improper and inaccurate assumptions about the size of the populations served by the particular pharmacies. Specifically, to estimate the size of the populations served by the particular pharmacies he studied, he relied on census data for West Virginia from 2010. Ex. B at 138:9-11; Ex. A at 39, 41, 42, 57, 63, 72. In most cases, he simply used the population of the town where the pharmacy was located as a proxy for the size of the population served by the pharmacy. But there is no basis to conclude that this measure accurately reflects the actual size of the population served by a particular pharmacy. By making this assumption, Dr. Siegel fails to account for numerous factors that impact the actual population served by the pharmacy, such as the pharmacy's geographic location, movement of people through the towns in which the pharmacy is located, and other factors like proximity to large hospitals, all of which would greatly increase the size of the population served. This inaccurate count, in turn, resulted in a much higher assumed per-person number of dosage units being distributed to the pharmacies Dr. Siegel studied, ultimately leading him to conclude that the distributions exceeded the nationwide threshold he had assumed.

Dr. Siegel himself readily acknowledged these shortcomings at numerous times during his deposition. As an initial matter, he notably did not render an opinion about "oversupply" as it relates to any pharmacy in Huntington, because, as he conceded, he could not reliably establish the size of the population served by any pharmacy there. Indeed, in discussing opioid distributions in Huntington, he recognized in his deposition testimony the problem with assuming that a town's population reflects the population served by a given pharmacy. He acknowledged that "if you do that for Huntington, because there's so many pharmacies, each

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health expert and an epidemiologist, I have expertise in many different areas of public health and those are all important areas in public health.").

pharmacy is not supplying the entire City, obviously." Ex. B at 36:10-12. This underscores the lack of any basis whatsoever for his assumption that a town's population measures the population served by any pharmacy, and highlights a central flaw in his methodology—population in an area defined by municipal boundaries is not an accurate reflection of the population served by individual pharmacies.

In assuming that his five Cabell County pharmacies served only the population of the very small towns where they are located, Dr. Siegel overlooked key factors that have a profound impact on the size of the population actually served by those pharmacies. For example, Dr. Siegel overlooked the existence of major roads and highways that pass through several of the towns, like Milton, WV (where CVS 10566 and Fruth 5 are located),[6] Williamson, WV (where Hurley Drug Company is located),[7] Mount Gay-Shamrock, WV (where Family Discount Pharmacy is located),[8] and Lesage, WV (where The Medicine Chest is located).[9] These major thoroughfares likely bring hundreds, if not thousands, of non-residents through these towns every

[6] Ex. B at 312:23-313:10, 314:8-12 ("Did you know that Interstate 64 runs through Milton? A. Yes. Q. Do you know how many people travel into Milton on Interstate 64 on an average day? A. I don't know. Q. Do you know that U.S. Highway 60 runs through Milton? A. Yes. Q. Do you know how many people travel into Milton on U.S. Highway 60 on an average day? A. I do not know that, no…. Q. Your report did not take into consideration the number of people who travel into Milton on an average day, correct? A. I mean, no, I guess I would say no, it didn't.").

[7] Ex. B at 316:4-13 ("Q. Did you know that Williamson is at the intersection of U.S. Routes 52 and U.S. Route 119? A. Yes. Q. Do you know how many people travel into Williamson on an average day? A. No. Q. Your report did not take into consideration the number of people who travel into Williamson on an average day, correct? A. Correct.").

[8] Ex. B at 317:9-18 ("Q. Did you know that U.S. Route 119 runs through Mount Gay-Shamrock? A. Yes. Q. Do you know how many people travel into Mount Gay Shamrock on an average day? A. No. Q. Your report did not take into consideration the number of people who travel into Mount Gay-Shamrock on an average day, correct? A. Correct.").

[9] Ex. B at 337:17-338:5 ("… In fact, would you agree that [Lesage is] one of the larger towns of the eight in Cabell County? A. Yes. Okay. It sits on Route 2; is that right? A. Yes. Q. And would you agree that Route 2 is a primary roadway that runs through Cabell County? A. Yes. Q. Okay. It is the road that takes you from northern Cabell County into Huntington. Is that right? A. Exactly."); Ex. B. at 341:8-15 ("Q. Do you know the population of people who would be using the Medicine Chest Pharmacy in the northern part of Cabell County? A. No, not specifically. Q. And you don't know if there would be people outside of the town of Lesage who may be using that pharmacy as they travel down Route 2. A. Not for certain, no.").

day, and often connect major population and employment centers in West Virginia, like the two largest cities of Charleston and Huntington, where those non-residents may work or conduct other activities. Ex. B at 314:1-4. This failure to account for a significant population of non-resident customers that pass in close proximity to the pharmacies in question entirely undermines the accuracy of Dr. Siegel's calculations because he clearly undercounted the size of the population served by each of these pharmacies. This, in turn, falsely inflates his ultimate conclusions about "oversupply."

Dr. Siegel also overlooked the presence of major hospitals—yet another source of non-resident potential customers—in close proximity to several of the pharmacies he included in his report. Indeed, Dr. Siegel acknowledged the amounts of prescription opioids shipped to a pharmacy would be significantly affected by its proximity to hospitals and other medical facilities. Ex. B at 329:13-17 ("I can't remember if I said this, but the relative location of medical facilities, large hospitals, large medical centers, cancer centers, I think is—is something that needs to be considered."). Yet, despite acknowledging this, Dr. Siegel's report does not account for patients and employees of hospitals that are two of the largest private employers in West Virginia: Cabell-Huntington Hospital and St. Mary's Medical Center. Ex. B at 342:1-21 (acknowledging that those two hospitals employ thousands of people—all of whom routinely travel throughout West Virginia on the highways discussed above to get to and from work); 183:8-184:3 (discussing the closest hospitals to the towns with pharmacies that Dr. Siegel analyzed).

Beyond failing to account for hospitals near the pharmacies he studied, Dr. Siegel also failed to analyze the effect of the VA Medical Center in Huntington on the populations served by the nearby pharmacies. When asked about this significant omission, Dr. Siegel conceded that he

was not capable of properly accounting for this factor. Ex. B at 222:11-19 (recognizing that "it would be a very difficult calculation, because … the VA is located in Huntington, it's very difficult to say, 'Well, okay, what is—what exactly is the population base for—you know, for that hospital.' So it would be a very difficult calculation to do, and I'm not sure I could make that assessment"). And Dr. Siegel failed to account for the impact of the VA Medical Center on the supply of opioids going to nearby pharmacies. The presence of these hospitals and their patients and employees has an effect—and Dr. Siegel does not know the effect—on both the demand and corresponding supply of opioids to the pharmacies near them. *See, e.g.* Ex. B at 223:19-22 (acknowledging that Dr. Siegel does not know the effect of backing out the supply of opioids related to the VA Medical Center in Cabell County).

Beyond the fact that it skews the populations served by individual pharmacies, the presence of the VA Medical Center in Huntington also undermines Dr. Siegel's population-based calculations of the aggregate opioid distribution into Cabell County (*see, e.g.*, Ex. A at 42). He readily acknowledged in his deposition that VA hospitals have a population base that is significantly higher than other hospitals. In particular, the VA in Huntington serves a population that includes southern West Virginia, southern Ohio, and eastern Kentucky. Because of that, Dr. Siegel's per-adult calculation of the number of dosage units of opioids distributed into Cabell County (which is based on the County population) is distorted by the fact that the VA serves far more than the population of Cabell County, *see generally* Ex. B at 225:6-226:4. And it is further distorted by the fact that patients served by VA hospitals have a higher average need for prescription opioids than does the general population. Ex. B at 228:12-16. Dr. Siegel in fact agreed that both Cabell-Huntington Hospital and St. Mary's Hospital also have a reach beyond the communities in which they are located, and even beyond West Virginia. Ex. B at 227:21-

228:11 ("In terms of your evaluation of distributors who supplied to Cabell-Huntington Hospital and St. Mary's Hospital, did you conduct any evaluation to your methodology to account for the fact that they service an area broader than simply Cabell County? A. No.").

Taken together, these methodological defects result in a dramatic undercounting of the population actually served by the pharmacies Dr. Siegel studied. By undercounting, Dr. Siegel artificially increased his estimates of the per-person number of opioids being distributed to those pharmacies. These errors are not something that can be clarified on cross-examination. Instead, they are a profound methodological flaw that require exclusion of his calculations.

Estimates about nationwide benchmarks. Beyond his assumptions about the population served by particular pharmacies, the second assumption of Dr. Siegel's methodology is a "national benchmark" of opioid use by adults. This assumed benchmark is similarly unreliable. Specifically, Dr. Siegel based his benchmark on the number of adults aged 20 and over who used a prescription opioid *in the past 30 days*, rather than the number who used opioids in the past year. *See* Ex. A at 35-36. Dr. Siegel explained that he used this 30-day number, rather than usage over a year's time, because he was "trying to give a sense of how many opioid doses are being used on an average day by people who are chronically taking prescription opioids." Ex. B at 144:4-7. But he readily agreed that this 30-day number understates overall usage of prescription opioids for acute pain, and that "[i]f you wanted to understand both acute and chronic pain, how many people used prescription opioids in a given year, . . . then you would use the whole year." Ex. B at 146:7-18.

Dr. Siegel's national benchmark thus understates and artificially lowers the total number of opioid-taking adults, by his own admission. To justify this obvious flaw in his methodology, Dr. Siegel asserted that he "could only find data for use in the past month," as opposed to the

past year. Ex. B at 141:14-15. Yet, when presented with such data (which is readily available and published by the U.S. Department of Health and Human Services, Ex. B at 150:8-17), he agreed that the percentage of opioid-using adults in the United States in the past year would increase to 37.8%, compared to his assumed benchmark of 6.9%. The more accurate annual benchmark fundamentally alters Dr. Siegel's conclusions. Under the more accurate benchmark, the rate of doses per prescription opioid taking adult does not exceed the national benchmark (even after the benchmarks were adjusted to reflect the increased percentage of population that was an opioid-using adult). Ex. B at 157:16-158:5; Ex. C (Siegel Dep. Exhibit 23). And even after adjusting for market share, using the more accurate benchmark yields a significantly lower rate of doses per prescription opioid taking adult than the analysis in Dr. Siegel's report. Stated differently, had Dr. Siegel used the more accurate annual benchmark, the numbers that drive his purported "oversupply" conclusions would have been much lower.

In the simplest terms, Dr. Siegel's analysis is a comparison of two pieces of data: alleged supply of opioids to individuals in Cabell County on the one hand, and to the entire country on the other. Dr. Siegel aspires to show the former is high and the latter is low. But Dr. Siegel has botched the math on both sides. He inflated the Cabell County numbers (by vastly undercounting the relevant population) and minimized the nationwide numbers (by ignoring large swathes of people who have taken prescription opioids). Both sides of Dr. Siegel's "oversupply" calculations suffer from a "garbage in, garbage out" problem that renders them unreliable, and they should be excluded.

C. Dr. Siegel's Opinions About "Oversupply" Are Unreliable

Beyond the inherent flaws of his methodology, Dr. Siegel's opinions should also be excluded because his overarching conception of "oversupply" is unreliable. His entire method is based merely on counting the number of prescription opioids distributed to particular

pharmacies, without taking into account the medical needs of the population served by that pharmacy, without any consideration of the demographics of that population, without any consideration of nearby hospitals and medical facilities, and without any other evaluation of the factors that would bear on whether the volume of pills shipped to a particular pharmacy is indeed an "oversupply." In particular, there is no medical or industry standard for determining "oversupply," nor does Dr. Siegel explain why his particular definition should be treated as reliable. Indeed, he conceded that no peer-reviewed study has ever used his methodology or anything analogous to identify an "oversupply" of opioids. Ex. B at 118:22-119:7. This means that Dr. Siegel's opinion about a purported "oversupply" of opioids is, in fact, nothing more than his own say-so, and is not, in fact, based on a reliable, established methodology. *See General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) (recognizing that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

In addition to this basic conceptual problem, Dr. Siegel also admits that the "oversupply" label is largely meaningless, because he has no way of identifying whether the allegedly oversupplied opioids were, in fact, subject to a legitimate prescription or going to a legitimate use. Ex. B at 109:4-15. When pressed on this point, he made the blanket assertion that any distribution above his threshold was, in fact, illegitimate:

> Q. And how many of – if you know, how many of the alleged "oversupply" of prescriptions to the pharmacies you analyzed then for Cabell County were medically illegitimate? Do you know?
>
> A. Well, I mean, my estimate would be that based on the comparison of the distribution of opioids into Cabell County to the national average, that anything over 50 percent of the national average would represent clearly supply that is not legitimate, that is – that is contributing to – that is being used for nonmedical legitimate purposes.

Ex. B at 109:16-110:3. But he then readily admitted that he did not—and could not—undertake to determine whether any of those prescriptions were, in fact, illegitimate. *See* Ex. B at 110:12-14 ("I mean, you can't – you can't necessarily look at a prescription and know whether it's legitimate or not. It's impossible."). His conception of "oversupply" is, by definition, unreliable, because it is concededly based on an arbitrary—and flawed—assumption that cannot be checked.

D. Dr. Siegel's Conclusions About Distributors' Public Health Responsibility Are Improper Legal Conclusions And Are Unreliable

Dr. Siegel's separate opinion that Distributors have a "public health responsibility" to prevent "oversupply" is also unreliable, for two reasons.

First, Dr. Siegel offers no basis for the existence of the supposed duty he posits. He cites no statute or regulation that imposes this responsibility as a matter of law, nor does he point to any other binding authority that sets forth his conception of public health responsibilities or requires Distributors to comply with them. Instead, his report cites only a WHO guideline that states "All parties involved in the distribution of pharmaceutical products have a responsibility to *ensure that the quality of pharmaceutical products and the integrity of the distribution chain is maintained* throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent." Ex. A at 20 (emphasis in original) (internal quotation marks omitted). This, of course, does nothing to support his claimed oversupply-prevention duty for Distributors.

The same is true of the other scattered documents Dr. Siegel cites. He points to statements of policy from industry organizations like the Healthcare Distribution Alliance (HDA) and its predecessor the Healthcare Distribution Management Association (HDMA), as well as from the Distributors themselves, *see* Ex. A at 22-32, but none of these documents

support the existence of a public health duty to prevent "oversupply." Dr. Siegel admitted that the HDA and HDMA statements are merely a "very general description" of the "responsibility to ensure the integrity of … the distribution chain." Ex. B at 237:4-10. And, with respect to the documents and policies by the Distributors themselves, Dr. Siegel conceded that he did not conduct an evaluation of whether or not the companies followed their controlled substance policies. Ex. B at 236:18-21.

When asked about the lack of supporting authority, Dr. Siegel reported that this is the first time he has ever written about a public health responsibility of this nature, Ex. B at 235:4-7, and that he is not aware of any other publications outlining the public health responsibilities of prescription opioid distributors. Ex. B at 235:16-20. This is telling, and demonstrates why his notion of a "responsibility" is unreliable and should not be admitted at trial. Dr. Siegel's "oversupply" responsibility was invented for this litigation, and it lacks any reliable basis. *See Salazar v. United States*, No. 01-0617, 2003 WL 25695854, at *3 (S.D.W. Va. Feb. 18, 2003) (Faber, J.) ("In fact, because this litigation is the first instance in which Dr. Eck has utilized the method. . .[that] militates against the reliability of the methodology used.").

Second, even if Dr. Siegel's opinion about the existence of a public health responsibility were based on something more than personal opinion, it still should be excluded because it is a legal conclusion that an expert may not offer. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."). Here, that is exactly what Dr. Siegel is doing. He assiduously avoids using the word "duty," but his opinion states quite clearly his unsubstantiated belief that Distributors had a legal obligation to protect the public health by preventing "oversupply." And, when viewed in the context of his broader opinions on

"oversupply," his conclusion is that Distributors failed in that duty. An expert cannot opine on such topics, as such legal conclusions usurp the role of the factfinder.

In at least one other case, Dr. Siegel's opinions on corporate duties have been excluded for the very reasons discussed above. *See In re E.I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 897, 914 (S.D. Ohio 2015) ("The Court also excludes Dr. Siegel's opinions related to the 'general duty of care that any company would be expected to fulfill.'"). As the *DuPont* Court rightly recognized, "[t]here is no special expertise necessary to make these determinations," and those determinations should be made by the factfinder, not presented by experts. *Id.* at 915. Like in *DuPont*, Dr. Siegel's legal conclusions on duty must be excluded.

For both of these reasons, Dr. Siegel's opinions about a purported "public health responsibility" should be excluded.

CONCLUSION

For the foregoing reasons, this Court should exclude the testimony of Plaintiffs' "oversupply" expert Dr. Michael Siegel.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 30th day of October, 2020 the foregoing **Memorandum of Law in Support of Defendants' Motion to Exclude Expert Testimony from Dr. Michael Siegel Regarding Purported Opioid "Oversupply"** was served using the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

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